IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS WACO DIVISION

| THERMOLIFE INTERNATIONAL, | § § | |
|------------------------------|--------|--------------------------------|
| LLC, | § | Civil Action No. 6:21-cv-00144 |
| | § | |
| Plaintiff, | § | JURY TRIAL DEMANDED |
| | § | |
| v. | § | |
| | § | |
| HUMAN POWER OF N COMPANY, | § | |
| d/b/a HUMANN, f/k/a NEOGENIS | § | |
| LABS, INC., | § | |
| | § | |
| Defendant. | | |

COMPLAINT

ThermoLife International, LLC ("ThermoLife" or "Plaintiff") brings this patent infringement action against Defendant Human Power of N Company, d/b/a HumanN, f/k/a/Neogenis Labs, Inc. ("HumanN" or "Defendant") as follows:

NATURE AND BASIS OF THE ACTION

- ThermoLife brings this civil action for infringement of United States Patent Nos. 9,180,140
 ("'140 Patent") (Exhibit 1), 8,455,531 ("'531 Patent") (Exhibit 2), and 10,555,968 ("'968
 Patent") (Exhibit 3) (collectively, the "Asserted Patents") under the patent laws of the United States, 35 U.S.C. § 1 et seq.
- 2. The Asserted Patents generally regard compositions comprising amino acids, nitrates, and/or nitrites and their uses, such as, but not limited to, reducing oxygen consumption and enhancing physical performance during exercise.

- 3. Without license or other authorization, HumanN has been directly and/or indirectly through inducement or contribution willfully making, marketing, offering for sale, and selling in the United States compositions of amino acids, nitrates, and/or nitrites covered by the Asserted Patents and/or for uses covered by the Asserted Patents.
- 4. This action seeks remedy for HumanN's willful infringement of the Asserted Patents, including, *inter alia*, monetary damages and injunctive relief.

THE PARTIES

- 5. ThermoLife is an Arizona Limited Liability Company, having its principal place of business at 1334 E. Chandler Blvd, #5-D76, Phoenix, Arizona 85048.
- 6. ThermoLife is a raw material supplier for dietary supplements in the United States, and an innovator in amino acid, nitrate, and nitrite technology.
- 7. ThermoLife has made significant investments to develop novel and innovative supplement compositions and their uses.
- 8. On information and belief, Human Power of N Company is a Texas company (Texas Taxpayer Number 32040136361; SOS File Number 0801160498) having, according to State of Texas records, its registered place of business at 1250 S Capital of Texas Highway, Building 1-360, West Lake Hills, Texas 78746-6312.
- 9. On information and belief, Human Power of N Company also has a regular and established place of business at 1122 S Capital of Texas Hwy Suite 300, Austin, TX 78746.
- 10. On information and belief, according to State of Texas records, the registered agent for Human Power of N Company is Joel J. Kocher, HumanN's President, whose registered address for service is 1122 S Capital of Texas Highway, Suite 300, Austin, Texas 78746.

- 11. On information and belief, Human Power of N Company does business as "HumanN" and was formerly known as Neogenis Labs, Inc. until changing its corporate name in April 2016 to "Human Power of N Company" without any other effect on corporate identity or liabilities under the laws of the State of Texas.
- 12. ThermoLife previously filed suit against HumanN in the District of Arizona (2:16-cv-02070) on June 27, 2016 for infringement of the '140 Patent (the "Prior '140 Proceedings"). Before HumanN answered the complaint in that case, the case was voluntarily dismissed without prejudice by ThermoLife in January 2018 for reasons related solely to then-newly-issued Supreme Court precedent concerning proper venue in patent cases. The complaint in the Prior '140 Proceedings and all exhibits thereto are attached (as **Exhibits 7, 7A-7J**) and incorporated herein to the extent discussed below.

JURISDICTION AND VENUE

- 13. The Court has subject matter jurisdiction over these claims under 28 U.S.C. §§ 1331 and 1338(a) and the patent laws of the United States, 35 U.S.C. § 1 *et seq.*
- 14. The Court has personal jurisdiction over HumanN because its principal place of business is in Texas, it is incorporated in Texas, it has availed itself of the rights and benefits of Texas law, and it has engaged in substantial and continuing contacts with Texas.
- 15. Venue is proper in the Western District of Texas pursuant to 28 U.S.C. § 1400(b) because HumanN is incorporated in Texas, maintains a principal and regular and established place of business in this District, and for the additional reasons discussed herein.
- 16. On information and belief, HumanN transacts business and has committed acts of infringement in this District, including, but not limited to, making, using, offering for sale, and selling supplement products without license or other authorization in contravention to

the Asserted Patents and/or inducing and/or contributing to at least one such act of infringement.

THE ACCUSED PRODUCTS

- 17. On information and belief, Defendant HumanN has used amino acid, nitrate, and nitrite technology in its commercial dietary supplements, which include, but are not limited to, those sold under the "SuperBeets"; "BeetElite"; and "Neo40" tradenames (the "Accused Products"). *See* Exhibits 4-6. To the extent that HumanN directly, or indirectly through inducement or contribution, makes, uses, offers for sale, or sells, or made, used, offered for sale, or sold, other products that fall within the scope of one or more claims of the Asserted Patents, ThermoLife also accuses those products as well.
- 18. On information and belief, HumanN formulates, makes, uses, manufactures, ships, distributes, advertises, promotes, offers for sale, sells, and has sold the Accused Products throughout the United States, including this District. *See* Exhibits 4-6.
- 19. On information and belief, all of the Accused Products include inorganic nitrates and inorganic nitrites, including nitrates from a botanical source. *See* Exhibits 4-6, 19-23.
- On information and belief, the Neo40 product also includes the amino acid citrulline, as indicated on the Neo40 product label and in HumanN's promotional material. *See* Exhibit6.
- 21. On information and belief, HumanN sells, offers for sale, and/or administers the Accused Products to customers through agreements arranged by telephone, over the Internet, and/or through distributors such as Amazon.com and GNC Corporation. *See* Exhibits 4-6.
- 22. On information and belief, since at least 2014, HumanN has engaged in certain "Promotional and Sales Activity" through labeling for the Accused Products, commercials,

advertisements, interviews, participation in and referrals to published studies, scientific claims, and/or websites (such as www.humann.com, www.neogenissport.com, www.neogenis.com, www.facebook.com/NeogenisSport, twitter.com/beetelite, and instagram.com/beetelite) wherein HumanN has directed, promoted, encouraged, instructed, contributed to, and induced the purchase, administration, and/or use of the Accused Products based on compositions covered by the Asserted Patents and/or methods covered by the Asserted Patents (such as the administration of an amount of inorganic nitrate and/or inorganic nitrite prior to exercise that will reduce oxygen consumption and enhance physical performance during exercise). *See* Exhibits 4-18.

23. At all times, HumanN made use of the claimed inventions in the Asserted Patents without authorization from or compensation to ThermoLife.

THE ASSERTED PATENTS

- 24. The '140 Patent is titled "Performance enhancing composition and use thereof" and has been reexamined by the Patent and Trademark Office. A true and correct copy of the '140 Patent post-reexamination is attached as **Exhibit 1**. The '140 Patent is valid and enforceable.
- 25. The '968 Patent is titled "Performance enhancing composition and use thereof." A true and correct copy of the '968 Patent is attached as **Exhibit 3**. The '968 Patent is valid and enforceable.
- 26. ThermoLife is the exclusive direct licensee of the '140 and '968 Patents and has all substantial and necessary right, title, and interest in the '140 and '968 Patents to bring this suit, including the right to use the patented technology without limitation, the right to issue any and all sublicenses for the '140 and '968 Patents without limitation, and the right to

- sue infringers such as HumanN and collect any and all past, present, and future damages for infringement of the '140 and '968 Patents.
- 27. ThermoLife owns the entire right, title, and interest in the '531 Patent. The '531 Patent is titled "Amino acid compositions" and has been reexamined by the Patent and Trademark Office. A true and correct copy of the '531 Patent post-reexamination is attached as **Exhibit 2**. The '531 Patent is valid and enforceable.

COUNTS OF PATENT INFRINGEMENT

28. Infringement by the Accused Products is discussed below in certain exemplary ways with respect to at least one patent claim for each Asserted Patent. Such discussion should not be considered limiting, and any additional infringing HumanN products and infringed claims of the Asserted Patents will be disclosed in compliance with the Court's scheduling order and/or the local rules related to infringement contentions. ThermoLife does not imply any particular claim constructions from the exemplary allegations below, any exhibit attached hereto, or any other language contained in this Complaint.

COUNT ONE(Infringement of the '140 Patent by all Accused Products)

- 29. ThermoLife repeats and realleges each of the allegations set forth above in paragraphs 1–28.
- 30. The '140 Patent regards a novel method for reducing oxygen consumption and enhancing physical performance during physical exercise by administering inorganic nitrate and/or inorganic nitrite.
- 31. Claim 1 of the '140 Patent recites:

A method for non-therapeutically reducing oxygen consumption (VO₂) of a human and enhancing physical performance of a human during physical exercise, the method comprising:

orally administering inorganic nitrate and/or nitrite to said human up to three days prior to the human performing physical exercise and in a dose of about 0.01-10 mmol inorganic nitrate/kg bodyweight/day and/or of about 0.001-1 mmol inorganic nitrite/kg bodyweight/day; wherein administration of said inorganic nitrate and/or nitrite will result in reduced oxygen consumption (VO2) in and enhanced physical performance of said human during the physical exercise as compared with the physical performance of said human during the physical exercise in the absence of administration of the inorganic nitrate and/or nitrite.

- 32. The information and allegations in the complaint in the Prior '140 Proceedings and exhibits to that complaint (**Exhibit 7, 7A-7J**) are expressly incorporated herein, except to any extent that they conflict with any information, position, or language contained herein.
- On information and belief, HumanN has directly infringed, or has committed induced or contributory infringement of, each and every limitation of claim 1 of the '140 Patent, literally and/or under the doctrine of equivalents, by making, using, promoting, advertising, selling, and/or offering for sale the Accused Products, including, *inter alia*, through HumanN's Promotional and Sales Activity.
- On information and belief, HumanN administers the Accused Products to its customers for oral consumption prior to performing physical exercise by selling the Accused Products to customers with direction, encouragement, urging, and instructions to orally consume a certain serving of each Accused Product daily and/or prior to exercise (the Accused Products' "Recommended Daily Dosages") that reduces oxygen consumption and enhances exercise performance. *See* Exhibits 4-7G; 8-10.
- 35. On information and belief, as disclosed in the '140 Patent (**Exhibit 1**), and as confirmed by information reported in scientific studies (**Exhibits 11-20**), including studies referenced and promoted by HumanN to its customers (**Exhibits 11-18**), and including studies on BeetElite and Neo40products (*see* **Exhibits 11, 19-20**), orally administering the claimed

amounts of about 0.01-10 mmol inorganic nitrate/kg bodyweight/day and/or about 0.001-1 mmol inorganic nitrite/kg bodyweight/day to a human (the "Claimed Amounts") will likely result in reduced oxygen consumption (VO₂) and enhanced physical performance of that human as compared to physical performance during physical exercise in the absence of that administration. For example, a public paper overseen by the leader of HumanN's Science Advisory Board (Dr. Jon Ivy, see https://www.humann.com/scienceoverview/leadership/) publicly reported that using one daily dose of Neo40 for three days resulted in a "meaningful tendency for less oxygen to be used during the [Neo40] treatment," "significantly lower [respiratory exchange rate] for the Neo40 treatment [that] seemed to be accomplished by the combine[d] effect of a little less oxygen consumption and much less carbon dioxide production (Tables 6 and 7)," and a "significant treatment effect on total work efficiency for [Neo40] compared to [placebo]," including "positive effect on extensor power recovery from the exhausting exercise," so that "in [the] study a slightly reduced oxygen cost combined with slightly more total work was connected to an enhanced work efficiency" and "three days of [Neo40] lozenge dietary nitrate has a positive effect on intense resistance exercise performance by enhancing ... increased work efficiency." See Exhibit 19 at 13-14, 17-18, 21, Tables 6-7; see also id. at Table 1 (summarizing findings of other studies—including several listed on HumanN's website demonstrating similar reduction in oxygen consumption (VO2) during exercise and increased exercise performance).

36. On information and belief, each Accused Product's Recommended Daily Dosage in oral form comprises amounts of inorganic nitrate and/or inorganic nitrite within the Claimed Amounts for at least Americans of average weight, assuming American male and female

mean bodyweights of approximately 89 kg and 77 kg respectively per CDC National Center for Health Statistics and the fact that approximately 1 mg inorganic nitrate = 0.0161 mmol inorganic nitrate and 1 mg nitrite = 0.0217 mmol nitrite. *See* Exhibits 4-6 (discussing instructions and daily dosage for each of the Accused Products, including their labels); Exhibits 21-23 (independent laboratory testing confirming amounts (in mg) of inorganic nitrate and inorganic nitrite in the Accused Products).

- 37. On information and belief, HumanN's customers include—and HumanN knows they include—at least some Americans of average weight or less who have orally consumed the Accused Products pursuant to HumanN's instructions, expectations, advertisements, promotions, and directions. *See* Exhibit 6 (male customer reporting personal weight to be "165lbs").
- 38. On information and belief, HumanN's administration of the Accused Products at the Accused Products' Recommended Daily Dosages therefore directly infringes claim 1 of the '140 Patent because it results in reduced oxygen consumption (VO₂) in and enhanced physical performance for at least some of HumanN's customers.
- 39. On information and belief, if HumanN's customers also administer the Accused Products to themselves directly, then at least some of them directly infringe claim 1 of the '140 Patent for the same reasons as discussed above with respect to HumanN's administration, and HumanN induces and/or contributes to that infringement.
- 40. Since at least when HumanN refused to license the '140 Patent before the Prior '140 Proceedings, and in no event later than service of the complaint in those proceedings, HumanN had specific knowledge of the '140 Patent and specific knowledge that administering the Accused Products at the Accused Products' Recommended Daily

Dosages reduces oxygen consumption (VO₂) and enhances physical performance in a manner that directly infringes at least claim 1 of the '140 Patent. *See* Exhibit 7 at 4-8; Exhibits 7H–7J.

- 41. On information and belief, HumanN specifically, knowingly, and willfully directed, intended, urged, induced, and/or encouraged its customers to commit such acts of direct infringement by purchasing the Accused Products and administering them within the Claimed Amounts resulting in reducing oxygen consumption and enhancing physical performance during exercise. *See* Exhibit 7 at 4-8; Exhibits 7H–7J.
- 42. On information and belief, HumanN specifically, knowingly, and willfully claims, markets, promotes, urges, expects, anticipates, induces administration of, and/or advertises the Accused Products at their Recommended Daily Dosages (and/or the Accused Products' relevant ingredients) for reducing oxygen consumption (VO₂) and enhancing physical performance during exercise as claimed in the '140 Patent, including, *inter alia*, through advertisements, sales channels, websites, commercials, interviews, marketing, customer testimonials, and/or references to published studies such as the following:
 - On HumanN's website: SuperBeets results in "improved energy and stamina" and "support[s] respiratory health through Nitric Oxide production" (Exhibit 4)
 - On HumanN's website: BeetElite "promote[s]" "Extended exercise endurance" and "Improved energy stamina"; "Promotes oxygen efficiency"; allows users to "Work out 18% longer," "use your oxygen more efficiently," "workout harder, go farther, do more work, and recover faster" (Exhibit 5)
 - On HumanN's website: Neo40 can "support respiratory health through Nitric Oxide production" and customer report that the product helped him to be "kept at my top level of fitness" (Exhibit 6)
 - Advertising BeetElite: "In 2009 a scientific study was conducted at the University of Exeter in the U.K. Eight men aged between 19 and 38

were given 500ml per day of beetroot juice for six consecutive days before completing a series of tests involving cycling on an exercise bike. On another occasion, they were given a placebo of blackcurrant cordial for six consecutive days before completing the same cycling tests. After drinking beetroot juice the group was able to cycle for an average of 11.25 minutes, which is 92 seconds longer than when they were given the placebo." (Exhibit 7A)

- In the Exeter study promoted by HumanN, the authors conclude that beetroot supplementation resulted in "7%–11% greater [power output] produced per liter of O₂ consumed," meaning that less oxygen would be consumed for the same amount of work after supplementation (**Exhibit 7B**)
- In a promotion for BeetElite: "Some researchers even surmise that nitrate may cause muscles to use oxygen more efficiently, thus requiring less during exercise"; "The cyclists performed better during the time trial, both riding faster and producing higher wattage, after consuming the nitrate-rich beet juice, and their oxygen uptake was reduced during the submaximal cycling." (Exhibit 7C)
- In a promotion for BeetElite: "Nitric oxide can improve blood flow, reduce oxygen cost to exercise, enhance muscle contractions, and help with glucose stability" (**Exhibit 7D**)
- In an advertisement for a BeetElite product: "But what is particularly exciting for cyclists is that beet juice has been proven to significantly boost on the-bike performance by increasing VO₂ max and oxygen efficiency—two keys for endurance." (Exhibit 7E)
- In an advertisement for a BeetElite product: "The nitrates in beet-root juice help the body process oxygen more efficiently, so you can generate more power before hitting your limit, especially during hard efforts." (Exhibit 7F)
- On HumanN's website: "Nitric oxide (N-O) ... may support healthy blood pressure and increasing nutrient and oxygen delivery to every system, organ, and tissue in the body" (Exhibit 7G)
- On HumanN's website: BeetElite "significantly reduces oxygen cost of exercise" and results in "improved oxygen efficiency" (Exhibit 8)
- From a HumanN commercial: SuperBeets results in "better oxygen efficiency," allows the body to "more efficiently ... use oxygen to generate energy," and "promotes energy and stamina for peak performance" (Exhibit 9)

- From a HumanN advertisement: Neo40 allows "better oxygen transfer and more energy" and "more endurance and better performance when exercising" (Exhibit 10)
- From a BeetElite study referenced on HumanN's website: consumption resulted in increased "Skeletal Muscle Oxygen Percentage" and increased "average time to exhaustion" (Exhibit 11)
- From HumanN's website, a list of "Studies on Health Benefits of Beet Juice," which include **Exhibits 13-15**, promoted and linked to from sales pages for the Accused Products (**Exhibit 12**) ("Linked Studies")
- In one of the Linked Studies: nitrates from "a single dose of [beetroot] lowered VO₂ during submaximal exercise and enhanced [time trial] performance" (**Exhibit 13**)
- In one of the Linked Studies: after administration of beetroot, "average VO₂ over [trial time] was significantly lower" and "significantly enhanced [trial time] performance" was observed (**Exhibit 14**)
- In one of the Linked Studies (**Exhibit 15**), a broad summary of studies (including **Exhibits 16-18**) reporting, *inter alia*, that nitrate/beetroot consumption reduces VO₂ and enhances exercise performance
- 43. On information and belief, the Accused Products are not suitable for noninfringing uses, HumanN knows that they are not suitable for noninfringing uses, and HumanN has never publicly disclosed noninfringing uses; when taken as directed at the Recommended Daily Dosages, the Accused Products provide inorganic nitrate and/or inorganic nitrite within the Claimed Amounts and reduce oxygen consumption and enhance physical performance as required by at least claim 1 of the '140 Patent.
- 44. On information and belief, the Accused Products are especially manufactured for and adapted by HumanN's customers to practice claim 1 of the '140 Patent—both facts known to HumanN; when taken as directed at the Recommended Daily Dosages, the Accused Products provide inorganic nitrate and/or inorganic nitrite within the Claimed Amounts

- and reduce oxygen consumption and enhance physical performance as required by at least claim 1 of the '140 Patent.
- 45. On information and belief, the inclusion of inorganic nitrates and/or inorganic nitrites in the Accused Products is material to practicing claim 1 of the '140 Patent, and their inclusion at the levels for practicing the methods claimed in the '140 Patent is essential to the Accused Products' function and purpose, represents the entire value therein, and drives sales of the Accused Products and complementary products sold by HumanN. *See* Exhibits 4-6.
- 46. On information and belief, without license or permission, HumanN has literally and/or through the doctrine of equivalents infringed, and continues to infringe, at least claim 1 of the '140 Patent in violation of 35 U.S.C. § 271(a) by administering the Accused Products as discussed, and/or HumanN has induced and/or contributed to such direct infringement of at least claim 1 of the '140 Patent by customers who administer the Accused Products as discussed, and continues to induce and/or contribute to such infringement, in violation of 35 U.S.C. §§ 271(b)-(c).
- 47. On information and belief, ThermoLife's licensees and/or its customers compete with HumanN in the United States.
- 48. On information and belief, because of HumanN's infringement, ThermoLife and/or its licensees and/or its customers have suffered, and will continue to suffer, monetary damages and lost profits, along with irreparable harm that warrants injunctive relief.
- 49. On information and belief, and for the reasons discussed, HumanN's infringement of at least claim 1 of the '140 Patent has been deliberate and willful, and an award of treble damages and attorney fees is warranted at least under 35 U.S.C. §§ 284, 285.

COUNT TWO

(Infringement of the '531 Patent by the Neo40 product)

- 50. ThermoLife repeats and realleges each of the allegations set forth above in paragraphs 1–28.
- 51. The '531 Patent regards novel amino acid compositions and methods related to their novel uses.
- 52. Claim 62 of the '531 Patent recites:

A solid supplement formulation comprising:

at least one non-ester nitrate compound; and

at least one isolated amino acid compound selected from the group consisting of Agmatine, Beta Alanine, Citrulline, L-Histidine, Norvaline, Ornithine, Aspartic Acid, Cysteine, Glycine, Lysine, Methionine, Proline, Tyrosine, and Phenylalanine,

wherein the at least one isolated amino acid is a separate compound than the at least one non-ester nitrate compound.

- 53. On information and belief, HumanN has made, used, marketed, promoted, advertised, offered for sale, and sold the Neo40 product. *See* Exhibit 6.
- 54. On information and belief, the Neo40 product infringes each and every limitation of at least claim 62 of the '531 Patent, literally and/or under the doctrine of equivalents.
- 55. On December 2, 2020, HumanN stated to the United States District Court for the District of Arizona that its Neo40 product is a "supplement" that HumanN "creates and markets." HumanN's First Amended Answer and Counterclaims, Dkt. No. 117 at 39, 2:18-cv-02980-DWL (D. Ariz. Dec. 2, 2020) (Exhibit 24).
- On information and belief, HumanN's label for the Neo40 product is required by the FDA pursuant to at least the Dietary Supplement Health and Education Act to accurately list all ingredients therein and does so.

57. HumanN's promotional materials and label for the Neo40 product (reproduced below from https://shop.humann.com/products/neo40-daily?, *see* Exhibit 6) identifies the Neo40 product as a "Supplement" in solid "tablet" form and also identifies the isolated amino acid compound "L-citrulline" and "Beet Root Powder" as separate ingredients:

Neo40 Ingredients:

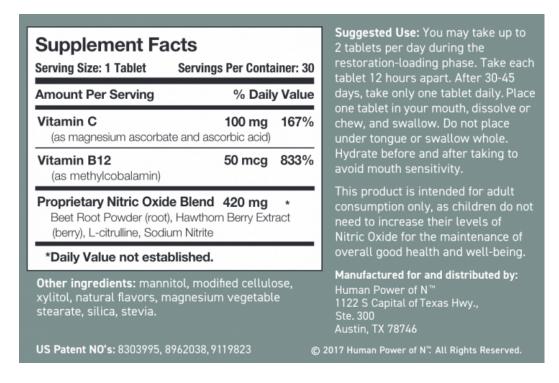
Vitamin C, Vitamin B12, Proprietary Nitric Oxide Blend (Beet Root Powder (root), Hawthorn Berry Extract (berry), L-citrulline, Sodium Nitrite.

Other Ingredients: mannitol, modified cellulose, xylitol, natural flavors, magnesium vegetable stearate, stevia, silica.

. . .

It's a 100% drug-free product that contains a blend of these powerful nitric oxide boosting ingredients:

- Beet Root Powder and Hawthorn Berry Extract: This combination provides two of the best building blocks your body needs to boost nitric oxide production.
- L-Citrulline: A rare amino acid that is essential to helping support nitric oxide production, particularly as you get older.
- **Sodium Nitrite**: Recent studies have shown that sodium nitrite is an important storage form and source of nitric oxide in the body and is a highly efficient form of delivery to support nitric oxide production.



58. On information and belief, a non-ester nitrate compound is present in the Neo40 product at least because of the inclusion of "Beet Root Powder (root)," an ingredient separate from the amino acid L-citrulline. *See also* Exhibit 23.

- 59. On information and belief, therefore, without license or permission from ThermoLife, HumanN has literally and/or under the doctrine of equivalents infringed at least claim 62 of the '531 Patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and selling the Neo40 product.
- 60. On information and belief, the inclusion of an amino acid compound and a non-ester nitrate compound in the Neo40 product is critical to the product's composition, function, and purpose, represents the entire value of the Neo40 product, and drives sales of the Neo40 product and complementary products sold by HumanN, including, but not limited to, other Accused Products. *See* **Exhibit 6**.
- 61. On information and belief, ThermoLife's licensees and/or its customers compete with HumanN in the United States.
- 62. On information and belief, because of HumanN's infringement, ThermoLife and/or its licensees and/or its customers have suffered, and will continue to suffer, monetary damages and lost profits, along with irreparable harm that warrants injunctive relief.
- 63. HumanN had specific knowledge of the '531 Patent and its infringement of the same prior to this Complaint because HumanN previously received a warning letter from ThermoLife about HumanN's infringement of the '531 Patent on December 30, 2016, and HumanN refused to stop its infringement or take a license thereafter.
- 64. On information and belief, and for the reasons discussed, HumanN's infringement of the '531 Patent has been deliberate and willful, and an award of treble damages and attorney fees is warranted at least under 35 U.S.C. §§ 284, 285.

COUNT THREE

(Infringement of the '968 Patent by the SuperBeets and BeetElite products)

- 65. ThermoLife repeats and realleges each of the allegations set forth above in paragraphs 1–28.
- 66. The '968 Patent regards novel nitrate/nitrite products.
- 67. Claim 45 of the '968 Patent recites:

A composition comprising:

a nitrite salt; and

- a botanical source of nitrate, wherein the nitrate from the botanical nitrate source is in a molar ratio of about 5:1 to 100:1 to the nitrite salt, wherein one dose of the composition provides said nitrite salt in an amount of about 0.001-10 mmol/kg bodyweight.
- 68. On information and belief, HumanN has made, used, marketed, promoted, advertised, offered for sale, and sold the SuperBeets and BeetElite products. *See* Exhibits 4, 5.
- 69. On information and belief, the SuperBeets and BeetElite products infringe each and every limitation of at least claim 45 of the '968 Patent, literally and/or under the doctrine of equivalents.
- 70. SuperBeets and BeetElite products are compositions.
- 71. Sodium nitrite is a nitrite salt. See, e.g., '968 Patent at claim 8.
- 72. HumanN has stated to the United States District Court for the District of Arizona that its SuperBeets and BeetElite products contain "substantial amounts of sodium nitrite." HumanN's First Amended Answer and Counterclaims, Dkt. No. 117 at 18-19, 2:18-cv-02980-DWL (D. Ariz. Dec. 2, 2020) (Exhibit 24).
- 73. On information and belief, the ingredients for BeetElite and SuperBeets products include a botanical source of nitrate (beets). *See* Exhibits 4, 5, 21, 22.

- HumanN has stated to the United States District Court for the District of Arizona that the "ingredients for BeetElite and SuperBeets" include "the highest quality beets that consistently exhibit high levels of dietary nitrates The beets are carefully selected; HumanN's suppliers test every new crop at the time of harvest for specific levels of dietary nitrate" HumanN's First Amended Answer and Counterclaims, Dkt. No. 117 at 40, 2:18-cv-02980-DWL (D. Ariz. Dec. 2, 2020) (Exhibit 24).
- 75. ThermoLife repeats and realleges each of the allegations set forth above in paragraphs 36 and 37.
- 76. HumanN has stated to the United States District Court for the District of Arizona the following regarding amounts of sodium nitrite and sodium nitrate in the SuperBeets and BeetElite products (HumanN's First Amended Answer and Counterclaims, Dkt. No. 117 at 19, 2:18-cv-02980-DWL (D. Ariz. Dec. 2, 2020) (Exhibit 24)):

[HumanN's] vendor's certified analysis illustrates that HumanN's products contain substantial amounts of sodium nitrite:

| CHEMICAL TEST: | | | | |
|------------------------------|------------|----------------|-------|--|
| Nitrites (as Sodium Nitrite) | <u>026</u> | 2,300 ppm Min | 2300 | |
| Nitrates (as Sodium Nitrate) | <u>026</u> | 25,000 ppm Min | 25200 | |

PPM converts to milligrams (1/1000 of a gram) by dividing it by 1,000. BeetElite has 10 grams per dose, while SuperBeets has 5 grams, so the per serving dose is ppm divided by 1,000, then multiplied by 10 for BeetElite (23 mg [sodium nitrite]) or 5 for SuperBeets (11.5 mg [sodium nitrite]).

According to HumanN's statements to the United States District Court for the District of Arizona, BeetElite has 252 mg of sodium nitrate per dose and SuperBeets has 126 mg of sodium nitrate per dose. *See* HumanN's First Amended Answer and Counterclaims, Dkt. No. 117 at 19, 2:18-cv-02980-DWL (D. Ariz. Dec. 2, 2020) (**Exhibit 24**); *see also* **Exhibits 21, 22**.

- 78. Sodium nitrate has a molar mass of 84.99 g/mol and sodium nitrite has a molar mass of 68.99 g/mol.
- On information and belief, therefore, according to HumanN's statements to the United States District Court for the District of Arizona, each serving dose of BeetElite contains 2.965 mmol of nitrate per serving dose and 0.3333 mmol of sodium nitrite per serving dose, which is an 8.9:1 molar ratio (botanical source of nitrate to nitrite salt), and, assuming average American body weights for males and females, each serving dose provides approximately 0.0037 mmol of sodium nitrite per kg bodyweight for average American males and 0.0043 mmol of sodium nitrite per kg bodyweight for average American females. *See also* Exhibit 22.
- 80. On information and belief, therefore, according to HumanN's statements to the United States District Court for the District of Arizona, each serving dose of SuperBeets contains 1.482 mmol of nitrate per serving dose and 0.1666 mmol of sodium nitrite per serving dose, which is also an 8.9:1 molar ratio (botanical source of nitrate to nitrite salt), and, assuming average American body weights for males and females, each serving dose provides approximately 0.00187 mmol of sodium nitrite per kg of bodyweight for average American males and 0.00216 mmol of sodium nitrite per kg bodyweight for average American females. *See also* Exhibit 21.
- 81. On information and belief, therefore, according to HumanN's statements to the United States District Court for the District of Arizona, without license or permission from ThermoLife, HumanN has literally and/or under the doctrine of equivalents infringed at least claim 45 of the '968 Patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and selling the SuperBeets and BeetElite products.

- 82. On information and belief, the inclusion of a botanical source of nitrate and a nitrite salt in the amounts stated by HumanN as being within the amounts claimed in the '968 Patent is critical to the SuperBeets and BeetElite products' composition, function, and purpose, represents the entire value of those products, and drives sales of those products and complementary products sold by HumanN, including, but not limited to, other Accused Products. *See* Exhibits 4, 5.
- 83. On information and belief, ThermoLife's licensees and/or its customers compete with HumanN in the United States.
- 84. On information and belief, because of HumanN's infringement, ThermoLife and/or its licensees and/or its customers have suffered, and will continue to suffer, monetary damages and lost profits, along with irreparable harm that warrants injunctive relief.
- 85. Upon information and belief, HumanN is known to track and have knowledge of ThermoLife's patents as and before they issue (including patents and applications in the same patent family as the '968 Patent). *See generally, e.g.*, HumanN's First Amended Answer and Counterclaims, Dkt. No. 117, 2:18-cv-02980-DWL (D. Ariz. Dec. 2, 2020) (Exhibit 24).
- HumanN had actual notice of its infringement of the '968 Patent as issued because ThermoLife's counsel sent HumanN's counsel a 35 U.S.C. § 154(d) warning notice for the then-allowed claims of the '968 Patent on December 27, 2019, which included the application number for the '968 Patent and a discussion of how the SuperBeets and BeetElite products would infringe based on HumanN's statements about the composition of those products. HumanN continued to make and sell the SuperBeets and BeetElite products after that notice.

When the Warranted at least under 35 U.S.C. §§ 284, 285.

DEMAND FOR JURY TRIAL

88. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, ThermoLife respectfully requests a trial by jury of any and all issues on which a trial by jury is available under applicable law.

RELIEF REQUESTED

WHEREFORE, ThermoLife respectfully requests the following relief:

- A. Judgment of infringement of the '140 Patent against HumanN;
- B. Judgment of infringement of the '531 Patent against HumanN;
- C. Judgment of infringement of the '968 Patent against HumanN;
- D. Enjoining HumanN and its officers, agents, servants, and employees, and all those persons acting in concert or participation, from further acts of infringement;
- E. An award of damages adequate to compensate ThermoLife for the infringement that has occurred, pursuant to 35 U.S.C. § 284, including prejudgment and post-judgment interest;
 - F. An award of treble damages for willful infringement pursuant to 35 U.S.C. § 284;
- G. An accounting and/or supplemental damages for all damages occurring after any discovery cutoff until the effectiveness of any decision enjoining further infringement;
- H. An award of attorney fees at least based on this being an exceptional case pursuant to 35 U.S.C. § 285, including prejudgment and post-judgment interest on such fees;
- I. Costs and expenses in this action, including prejudgment and post-judgment interest on such costs and expenses; and
- J. Any additional award of any additional relief, in law and in equity, as the Court deems just and reasonable.

Dated: February 11, 2021 Respectfully submitted,

/s/ Steve Udick

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